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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| Aldo J. Test DORSEY & WHITNEY LLP Suite 3400 4 Embarcadero Center San Francisco, CA 94111 | | EXAMINER WALLENHORST, MAUREEN | | |
| | | ART UNIT PAPER NUMBER 1743 | | |
| DATE MAILED: 04/30/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,080

Applicant(s)

KOCHY ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

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1. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 3 of claim 1, the phrase "said supporting plate or rack" lacks antecedent basis since the preamble of claim 1 only refers to a plate or rack. See this same problem on line 4 of claim 6.

On lines 2-3 of claim 4, the phrase "the suspended end of the capillary" lacks antecedent basis. See this same problem on lines 2-3 of claim 14.

Claim 5 is indefinite and incomplete since it is not clear where the stirrer is located in the cytometer system. Is the stirrer associated with the mechanism for sequentially translating individual sample containers? On line 1 of claim 5, the phrase "adapted to stir" is indefinite since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. See *In re Hutchison*, 69 USPQ 138. See these same problems in claim 15.

On line 2 of claim 9, the phrase "means for moving the mixes in the Z direction" does not make proper sense.

Claim 11 is indefinite since it is not clear whether the means for vibrating the capillary is the same as the mixing means.

Lines 8-10 of claim 14 are indefinite since these lines recite a method step involving the lifting and lowering of the mechanism for supporting the sample containers. These lines do not

make sense in the context of claim 14 since claim 14 recites an apparatus. Therefore, lines 8-10 should be rewritten as an apparatus limitation.

Claim 15 is redundant with claim 5 since it depends from claim 4 and recites the exact same limitation as claim 5.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kercso et al.

Kercso et al teach of a system for analyzing a large number of samples contained in standard multiwell plates or other array structures. In the system, multiwell plates 12 are moved on a conveyor to a test station 26 that includes a microfluidic device 40. An X-Y-Z robot arm 44 lifts a plate 12 from the conveyor and sequentially aligns the wells of the plate with a pipettor 46 extending downwardly from the microfluidic device 40. An optical detection system 48

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optically monitors an analyzing volume in the channel network of the microfluidic device 40.

The robotic arm 44 is able to move the plates in three dimensions. The arm lifts plates in the vertical or Z direction to transport the plates from the conveyor path 20 to the microfluidic device 40. This allows the microfluidic device to remain at a fixed location so that various optical and electrical components that interface with the microfluidic network do not have to be moved repeatedly. The robot arm positions a plate in the X-Y plane to sequentially align the wells of the plate with pipettor 46, thereby allowing the samples in the wells to be sequentially introduced into the channel network of the microfluidic device. Once the wells are aligned with the pipettor 46, the robotic arm can lift the plate to bring the sample in the aligned well into contact with the pipettor. The robotic arm 44 constrains a plate 12 by the use of a supporting tray or bracket 56 that fittingly engages the plate so that the plate can be moved both laterally and vertically. See columns 3-4, column 9, lines 33-67, column 10, lines 1-2 and column 13, lines 25-51, and figures 1-4 in Kercso et al.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of McNamara et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach that the X-Y-Z robot arm 44 comprises a motor driven cam and/or motor driven lead screws.

McNamara et al teach of a device containing probes 78 aligned with reaction containers 102 in a row of reaction containers. A tray 104 having a plurality of depressions arranged in rows and columns receives the reaction containers 102 that are placed in the depressions. The rack 104 rests on a platform 106 of a positioning means 108. The positioning means 108 employs a motor driven lead screw 110 for driving the platform 106 in a horizontal direction. Another motor driven lead screw 114 can vertically reciprocate the platform. The movement of the tray 104 by the positioning means 108 is sufficient to raise the platform 106, immerse a probe 78 into a reaction container 102 and then remove the probe. Platform 106 is also horizontally movable to allow probe 78 access to different reaction containers. See column 7, lines 11-41 and figures 5-6 in McNamara et al.

Based upon the combination of Kercso et al and McNamara et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the X-Y-Z robot arm 44 taught by Kercso et al with motor driven lead screws or an equivalently functional motor driven cam as the means for moving the arm in the X, Y and Z directions since McNamara et al teach that such means are conventional and useful in automatic devices to move a support tray holding a plate containing an array of multiple containers or wells in the horizontal and vertical directions.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Hewett et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach that the multiwell plates 12 contain therein cleaning wells for selectively receiving and cleaning the pipettor 46.

Hewett et al teach of an automated liquid handling apparatus comprising a support bed 10 upon which a horizontally reciprocal table 12 is indexable selectively to bring a rack 14 of pipette tips 30 into alignment with a selectable row of wells 34 on a multiwell plate or into alignment with a trough 45, 46 or 47 on the table 12. The troughs can contain a reagent therein or a wash liquid so that the pipette tips 30 can be brought into alignment with the wash troughs and washed between uses, thereby preventing one sample from contaminating another. Such washing allows the same tips to be used for a plurality of transfer steps without replacement or disposal of the tips. See lines 34-48 in column 3 and figure 1 of Hewett et al.

Based upon the combination of Kercso et al and Hewett et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the multiwell plates 12 taught by Kercso et al cleaning wells for selectively receiving and cleaning the pipettor 46, similar to the wash troughs 45, 46, or 47 in the apparatus of Hewett et al, since Hewett et al disclose that such cleaning wells or troughs in an automated liquid handling apparatus allow for the same pipette tips to be used for a plurality of liquid transfer steps without contaminating samples and without replacement or disposal of the tips.

9. Claims 5-6, 9-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Watts et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach of a mixing means associated with the pipettor 46.

Watts et al teach of an automatic chemistry analyzer 10 that comprises a sample probe arm assembly 80 as depicted in Figures 6a-6d. The sample probe arm assembly 80 includes a sample probe arm 82, a hollow sample probe 84 and a rotatable sample stirring rod 86 associated with the sample probe 84. The sample probe 84 is disposed generally vertically in the sample probe arm 82 and is movable by a sample probe motor 96 between a lower sample probe position and an upper sample probe position. The sample stirring rod 86 has a lower end 98, an upper end 100 and a stirring rod paddle 102. The sample stirring rod 86 is also disposed generally vertically in the sample probe arm 82 and is movable by a sample stirring rod motor 104 between a lower sample stirring rod position and an upper sample stirring rod position. The sample stirring rod is also operatively rotated by a sample stirring rod rotating motor 105. The raising and lowering of the sample stirring rod is independent of the raising and lowering of the sample probe 84. The sample stirring rod 86 and the sample probe 84 are raised and lowered using a rack and pinion assembly 106. Therefore, Watts et al teach of a mixing means associated with a capillary or probe that can mix a sample in a container into which the mixing means is immersed by the raising and lowering of the mixing means and the rotation of the mixing means. See lines 19-65 in column 9 and figures 6a-6d of Watts et al.

Based upon a combination of Kercso et al and Watts et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to associate a mixing means adjacent to the pipettor 46 taught by Kercso et al that has the ability to move in the Z direction, similar to the sample stirring rod 86 taught by Watts et al, since Watts et al teach that it is beneficial to mix a sample held within an array of wells or rack before the withdrawal of the sample by a pipette or probe so that the sample is homogenous and all analytes or components

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within the sample are evenly distributed. It also would have been obvious to one of ordinary skill in the art to surround the pipettor 46 taught by Kercso et al with the mixing means taught by Watts et al rather than adjacent to the pipettor 46 since such an embodiment is merely an obvious engineering change in form or shape that allows the pipettor 46 to move in conjunction with the movement of the mixing means rather than being independent of the mixing means.

10. Claims 5-6, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Nishi et al. For a teaching of Kercso et al, see previous paragraphs in this Office action. Kercso et al fail to teach of a mixing means associated with the pipettor 46 that can vibrate the pipettor.

Nishi et al teach of a vibrating pipette probe mixer 10. A support 15 serves to move the pipette 10 to a series of different reaction vessels 8 for adding microliter quantities of solutions to each reaction vessel while simultaneously mixing the liquids therein. See lines 3-40 in column 2 and figures 1 and 3 in Nishi et al. Therefore, Nishi et al teach of a mixing means associated with a capillary or pipette that serves to vibrate the capillary/pipette.

Based upon the combination of Kercso et al and Nishi et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to associate a mixing means with the pipettor 46 taught by Kercso et al that has the ability to vibrate the pipettor in order to provide a mixing action, similar to the mixing means taught by Nishi et al, since Nishi et al teach that it is beneficial to mix a sample held within a reaction vessel before the withdrawal of the sample by a pipette or probe so that the sample is homogenous and all analytes or components within the sample are evenly distributed.

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11. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Watts et al or Kercso et al in view of Nishi et al as applied to claims 5-6, 9-11 and 15 above, and further in view of McNamara et al. For a teaching of Kercso et al, Watts et al, Nishi et al and McNamara et al, see previous paragraphs in this Office action. The combination of Kercso et al with Watts et al and the combination of Kercso et al with Nishi et al both fail to teach that the X-Y-Z robot arm 44 in Kercso et al comprises a motor driven cam and/or motor driven lead screws.

Based upon the combination of Kercso, Watts et al and McNamara et al or the combination of Kercso et al, Nishi et al and McNamara et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the X-Y-Z robot arm 44 taught by Kercso et al with motor driven lead screws or an equivalently functional motor driven cam as the means for moving the arm in the X, Y and Z directions since McNamara et al teach that such means are conventional and useful in automatic devices to move a support tray holding a plate containing an array of multiple containers or wells in the horizontal and vertical directions.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al in view of Watts et al or Kercso et al in view of Nishi et al as applied to claims 5-6, 9-11 and 15 above, and further in view of Hewett et al. For a teaching of Kercso et al, Watts et al, Nishi et al and Hewett et al, see previous paragraphs in this Office action. The combination of Kercso et al with Watts et al and the combination of Kercso et al with Nishi et al both fail to teach that the multiwell plates 12 disclosed by Kercso et al contain therein cleaning wells for selectively receiving and cleaning the pipettor 46.

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Based upon the combination of Kercso, Watts et al and Hewett et al or the combination of Kercso et al, Nishi et al and Hewett et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the multiwell plates 12 taught by Kercso et al cleaning wells for selectively receiving and cleaning the pipettor 46, similar to the wash troughs 45, 46, or 47 in the apparatus of Hewett et al, since Hewett et al disclose that such cleaning wells or troughs in an automated liquid handling apparatus allow for the same pipette tips to be used for a plurality of liquid transfer steps without contaminating samples and without replacement or disposal of the tips.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Goix et al who teach of a capillary tube flow cytometer.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 28, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
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